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## ROUND THE CORNER

Most of us have seen the cartoon of an innocent blithely walking along the street: what he can't see but we can is the gorilla with the big club!

The club is the problem that the innocent will have to cope with when he turns the corner, though nowadays management speak turns the club into a challenge or an opportunity. In health care there are many 'opportunities', mostly driven by technology, and surprises do crop up with purchasers at all stages in the contracting cycle. In 1995 in *Bandolier* we will try to identify the surprises that lie around the corner, and perhaps try to provide some guidance on how these should be met.

### Putting up mirrors

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One way to see around the corner is to put up a mirror and the National Research and Development Programme is in the process of doing just that. In *Bandolier* we will be looking round the corner by getting information from a number of sources.

### Prescribing

We will be seeking information by monitoring newly licensed products, new advertising campaigns, new campaigns by pharmaceutical representatives and early changes in prescribing behaviour.

### Kitwatch

We monitor the development of new diagnostic tests and equipment by reading the trade journals which contain eloquent appreciations of new diagnostic technology, but too often without good solid evidence of effectiveness - not just that it works, but that having it work is of proven benefit to patients and/or care givers. Glossy pictures backed by assertion is too often the order of the day, with the only numbers being page numbers.

### Editorials

Editorials often cover established techniques, but also can herald new developments. For all the weaknesses inherent in the writing of editorials, and there are many, the editorial titles provide a useful monitoring tool.

### Reports from conferences

We will seek conferences reports attended by professionals; conferences are often used to 'launch' a product, where the challenge round the corner is first presented.

### Requests from readers

We very much welcome suggestions from readers, particularly those who have been "clubbed" by a new development in the middle of a financial year.

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## MÉNIÈRE'S DISEASE

Ménière's disease or Ménière's syndrome can be a disabling condition where hearing loss, tinnitus, vertigo and a feeling of fullness in the ear come together in various proportions and extents. *Bandolier* this month has examined the evidence concerning the incidence and prevalence of the disease; we have also run a search on MEDLINE for randomised controlled studies (RCTs) of treatments published since 1990 (using the terms Ménière and random\*). The only results have been for betahistine treatment, and these have been expanded by RCTs of betahistine trials in the 1980s.

### What is Ménière's Disease?

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The constant pathological finding in Ménière's disease is a progressive distension of the endolymphatic space of the inner ear. It appears that fluid build-up in the endolymphatic space (endolymphatic hydrops), caused either by overproduction or reduced absorption, exposes hair cells responsible for sensing movement and balance to progressive damage or paralysis. The result of that paralysis is that the person has an attack of dizziness, often with nausea and vomiting.

Early on these attacks can be short, as the damage to the hair cells is temporary and they can begin to function normally when the hydrops resolves. Repetitive insults lead to irreversible changes as the hair cells die; when dead they do not regrow, and hearing loss, in particular, can become permanent. There is an excellent recent review of Ménière's disease [1].

### What causes Ménière's Disease?

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The simple answer is that there is no simple answer. A review of over 300 articles published between 1983 and 1989 [2] covers many papers which look at the aetiology of Ménière's disease. One 'theme' in the reports on aetiology and pathology seems to be an increase in immunoglobulins both in the endolymphatic fluid and in serum, occurring in a high proportion of patients with Ménière's disease. While it is likely to be a multifactorial condition, some sort of underlying infection (probably viral) or auto-immune component seems likely in patients with this condition.

How is Ménière’s Disease diagnosed?

The usual clinical diagnosis is the triad of symptoms of vertigo, hearing loss and tinnitus, often with a feeling of fullness of the ear. The tinnitus and hearing loss are usually unilateral, and the disease at onset is often mild, with attacks lasting for an hour or so. In some patients, however, the onset can be much more serious, with trains of episodes resulting in significant nausea, vomiting and prostration.

Electrocochleography (ECOG) exposes the ear to a train of click or tonal stimuli recorded by an electrode situated close to the cochlea which records action potentials from the firing of auditory neurones. Endolymphatic hydrops results in a widening of the wave-form with multiple peaks that is quite different from the normal result [see 1]. This test is quite simple and can be carried out in most ENT centres.

How common is Ménière’s Disease?

There are a number of reports concerning the incidence and prevalence of Ménière’s disease. The numbers vary quite considerably from study to study, and quite clearly different diagnostic criteria have been used at different times and in different places.

In Northern Ireland, Wilmot [3] estimated from experience over a 25-year period that the incidence was between 1 and 2 cases per 10,000 population per year (say 200 cases per million).

Stahle and colleagues [4] estimated the incidence of Ménière’s disease in a Swedish population in 1973; this was possible because Ménière’s disease was recorded on the health records of all inpatients with the diagnosis in Sweden. A computer analysis was conducted in the Uppsala and Skåne parts of Sweden, with a combined population of over 2 million. In 1973, the two regions with a joint population of 2,263,285 had 257 patients diagnosed with Ménière’s disease (114 cases per million) of whom 60% were women, and most (228) cases were between 15 and 69 years.

Watanabe’s [5] paper on the incidence of Ménière’s disease in Japan also has some interesting historical data on incidence from the UK in the 1950s and 1960s; results from Oxford in the mid 1950s suggest an incidence of about 560 per million, though higher figures are also quoted.

In the 1970s nation-wide surveys on the incidence of

Incidence of Ménière’s Disease			
Study	Year	Population	Cases per million
[3]	1979	N Ireland	200
[4]	1973	Sweden	114
[5]	1977	Japan	160 or 35
[6]	1980	United States	153
[7]	1985	Italy	82

Ménière’s disease were carried out in Japan. Though they reveal much of interest about age and sex distributions, severity and other aspects of disease, the only national figure for incidence based on a one-day survey was 160 cases per million, though figures on a 1-week survey were much lower, at 35 per million.

In the United states, a very thorough study of the incidence and prevalence of Ménière’s disease was carried out in the population of Rochester, Minnesota, using a centralised diagnostic index at the Mayo clinic. This study examined cases between 1951 and 1980 [6]. The incidence of Ménière’s disease in 1980 was 153 cases per million of population. Median ages of onset and diagnosis were 50 and 53 years respectively, although half the cases were diagnosed within 6 months of onset. This is a most important paper giving useful information about this difficult disease. The prevalence of the disease was 2,182 per million.

A recent report from Siena [7] and Latium from two hospitals serving the needs of 104,000 people, over 13 years found 111 cases, almost all being diagnosed between the ages of 10 and 70 years, with a distinct peak between 40 and 50 years. This gives an incidence of 82 cases per million. Interestingly, the incidence was some 3 times higher in hospital workers than the general population, and the authors suggested that this may reflect a higher rate of diagnosis - and that the figures for the general population may be reduced by under-diagnosis.

What is the natural history of Ménière’s disease?

There does not seem to be a clear answer to this question. In some patients the unilateral disease appears to “burn-out” with deafness remaining but with the vertigo and tinnitus declining. Other patients (the minority, but perhaps up to 25%) go on to develop a severe bilateral disorder where the vertigo remains - and where ablation of the inner ear becomes necessary.

Can lifestyle changes help?

It is suggested that food allergy or excess caffeine, nicotine or alcohol may be in some way involved in the aetiology of Ménière’s disease. This is far from being proven. It is suggested that avoidance of caffeine, etc., may help. *Bandolier* has found no evidence of that in any RCT or other study.

Are there surgical treatments?

There are a number of surgical procedures [2], but *Bandolier* was not able to find randomised controlled trials of their effectiveness. We would be happy to report on such trials in future if any readers can bring them to our attention - computer literature searches are not infallible.

## Are there medical treatments?

Yes, there are a number, but the only RCTs that we could find referred to betahistine. The mechanism of action of betahistine appears to be by promoting better circulation in the microvasculature, leading to reduction in endolymphatic hydrops.

There are six RCTs with betahistine, and five involve treatment of Ménière's disease. These studies used different doses, and the outcome measures used were not usually dichotomous so a meta-analysis with numbers-needed-to-treat was not possible. Instead, *Bandolier* will give a brief report on each paper. The quality of the studies was generally high.

### Wilmot & Menon, 1976 [8]

This was a randomised double-blind cross-over comparison of betahistine 24 mg daily and placebo for 8 or 12 weeks. Twenty-four patients began the study and analysis was performed on 22 - there were two patients with worsened symptoms who did not complete the treatments.

Patients maintained a daily symptom card for vertigo, tinnitus, deafness, fullness of ear and vomiting. Betahistine produced significantly less severe vertigo, tinnitus and fullness of ear than did placebo.

### Frew & Menon, 1976 [9]

This RCT compared betahistine with placebo after a 4-week period on placebo followed by four 8-week periods with either betahistine 32 mg daily or placebo on two occasions each. Of 28 patients who began the treatment, 22 completed it, six being unable to co-operate, for reasons not given.

Symptom score cards were again used, and patient scoring showed significantly better results for vertigo and tinnitus.

### Fischer and van Elferen, 1985 [10]

Patients were recruited from general practitioners lists. 83 patients were finally selected, who after one month on placebo were randomly allocated to betahistine 48 mg daily or placebo for three months. Ten patients did not complete the study for a variety of reasons.

A battery of outcome measures was used, including number of attacks per month, mean duration of attacks and intensity and accompanying symptoms.

Betahistine proved to be significantly better than placebo for number, duration and intensity of attacks, with significantly more patients asymptomatic in the last month of treatment with betahistine compared with placebo.

This paper is also important because the authors examined the effectiveness of treatment with regard to duration of Ménière's disease in a post-hoc analysis. They found that, with betahistine, the patients who had complete relief had duration of symptoms less than a third as long as those

who still had symptoms. The message would seem to be start treatment early in the course of the disease for the best results.

### Deering et al, 1986 [11]

Another general practice study involved 88 patients in a cross-over design with betahistine 72 mg daily compared with cinnarizine 90 mg daily for three months on each treatment. Forty-six patients completed the full six month period; the most common reason for discontinuing betahistine was feeling better.

The frequency of attacks fell from a pre-treatment mean of 9 attacks per month to about 5 attacks per month with betahistine, and the mean duration of attacks was about half or less with betahistine (down from 1.3 to 0.5 hours on average). Betahistine was significantly better than cinnarizine.

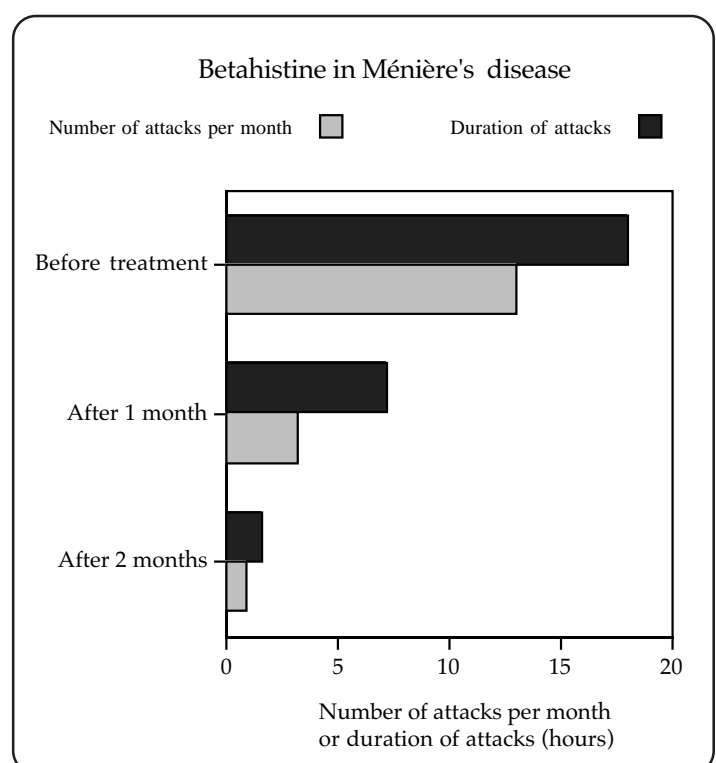
### Frayse et al, 1991 [12]

This GP study involved 55 patients treated for two months with betahistine 48 mg daily or flunarizine 10 mg daily in a parallel group design. There were six withdrawals for a variety of reasons.

Again a battery of outcome measures was used, including attack numbers, duration and intensity. Betahistine was better than flunarizine, and showed very large improvements in attacks over a period of two months, as shown in the Figure below.

### Betts et al, 1991 [13]

This RCT evaluated the effects of betahistine 216 mg daily, prochlorphenazine 15 mg and placebo, taken for three days, on driving skills in twelve volunteer subjects. The psycho-



motor effects of betahistine could not be distinguished from placebo.

In all the above studies, the incidence of adverse effects was low. There were 22 reports of adverse events in 19 patients on betahistine in study 11, where the dose of betahistine was somewhat higher than the 48 mg daily usually recommended, and drowsiness was the most frequent side-effect. The incidence of adverse events was low at 48 mg/day in study 12; drowsiness and gastrointestinal disorders occurred in 18% and 4% of patients respectively after two months of treatment.

## Conclusion

Ménière's disease is not common, but an average GP practice with some 6000 patients would expect to see perhaps one new case per year. A Health Authority of 250,000 would see some 60 cases per year.

The disease seems to strike in middle years, most commonly between 30 and 60 years, and to affect men and women about equally. The reasons for the onset and pattern of the disease are not yet understood.

There is an effective diagnostic test that should be available at all ENT clinics, and at least one effective medical treatment. Betahistine costs about £235 a year to maintain a patient on 48 mg daily; this cost has to be set against the cost of not treating patients who, untreated, may have up to 20 attacks of long duration per month, and consume much GP and specialist clinic time.

## References:

- 1 SR Saeed, AR Birzgalis, RT Ramsden. Ménière's disease. *British Journal of Hospital Medicine* 1994 51: 603-12.
- 2 J Dickens, SS Graham. Ménière's disease - 1983-1989. *American Journal of Otology* 1990 11: 51-65.
- 3 TJ Wilmot. Ménière's disorder. *Clinical Otolaryngology* 1979 4: 131-43.
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- 11 RB Deering, P Prescott, RL Simmons, LJ Downey. A double-blind crossover study comparing betahistine and cinnarizine in the treatment of recurrent vertigo in patients in general practice. *Current Medical Research and Opinion*. 1986 10: 209-214.
- 12 B Frayse, J-P Bebaer, C Dubreuil, C Berges, R Dauman. Betahistine dihydrochloride versus flunarizine. *Acta Oto-laryngologica* 1991, Supp 490: 2-10.
- 13 T Betts, D Harris, E Gadd. The effects of two anti-vertigo drugs (betahistine and prochlorperazine) on driving skills. *British Journal of Clinical Pharmacology* 1991 32: 455-8.

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## PLAQUE CONTROL

Oral hygiene has been targeted by manufacturers and advertisers in a big way in recent years, with numerous new products to reduce plaque and sweeten breath. Are they effective?

### Pre-brushing mouthwash - a controlled trial

Twenty subjects with tooth staining entered a double-blind placebo-controlled cross-over study [1]. They used a pre-brushing mouthwash (Plax) or a placebo for 14 days, followed by a one month 'washout' (sic) and then the alternative treatment. The area of stain was assessed before and after the use of each mouthwash from clinical photographs.

The percentages of stained areas (with blind assessment) changed very little throughout the study, with no statistical differences.

This paper also reports an in-vitro study on extracted third molar teeth. They were stained with either tea or chlorhexidine, and then brushed in a standardised manner after standard exposure to Plax or placebo. The mean area of staining fell after brushing by 19% after exposure to Plax and by 17% after exposure to placebo. There were no differences in staining intensity.

The results of this study do not support the marketing hype. Mouthwash containing alcohol has been linked to buccal cancers, and even though most products do not contain the high levels as seen in the past, if they don't work, why bother?

## Reference:

- DC Mills, SR Smith, L Chung. The effect of using a pre-brushing mouthwash (Plax) on removal of tooth stain in vivo and in vitro. *Journal of Clinical Periodontology* 1994 21: 13-16.

# ANTIMICROBIAL TREATMENT OF CYSTITIS

Urinary tract infections in women are a common reason for GP visits, and GPs use a large number of different antimicrobials for widely different times. A randomised controlled trial of four antimicrobial three-day regimens may help to put some evidence behind treatment.

## The setting

The study was carried out in Seattle among young women presenting to the University of Washington Student Health Centre. They had symptoms of acute cystitis including dysuria, frequency, urgency and/or suprapubic pain. E coli was the most common pathogen (85%), and no patient had chlamydia or gonorrhoea at enrolment.

## The design

Treatments were randomised but not blind. Each was for three days, and they were:-

- trimethoprim-sulphamethoxazole, 160 mg/800 mg, twice daily (co-trimoxazole in the UK).
- macrocrystalline nitrofurantoin, 100 mg four times a day.
- cefadroxil, 500 mg twice daily
- amoxycillin, 500 mg three times daily

Patients were seen before treatment began, at 4-6 days, 2 weeks after treatment and 4-6 weeks after treatment.

A genitourinary history was taken on each occasion and a mid-stream urine was collected for culture.

## The results

Trimethoprim-sulphamethoxazole proved to be the best treatment, with 82% of women cured at the six-week visit, and with the lowest remaining incidence of vaginal E coli (21%). Adverse events were reported by 35% of patients treated with trimethoprim-sulphamethoxazole, similar to other treatments.

The study also performed an economic analysis, showing that treatment with trimethoprim-sulphamethoxazole was the

least costly. Though drug costs will be different in the UK, the higher costs of the less effective treatments were associated with more frequent visits to the clinic for treatment of recurrent urinary tract infection.

In the UK, the cost of three-days course of the drugs is lowest for trimethoprim-sulphamethoxazole (co-trimoxazole; £0.42); for nitrofurantoin it is £0.48, for amoxycillin £0.75 and for cefadroxil £1.69), without dispensing fees.

## Conclusion

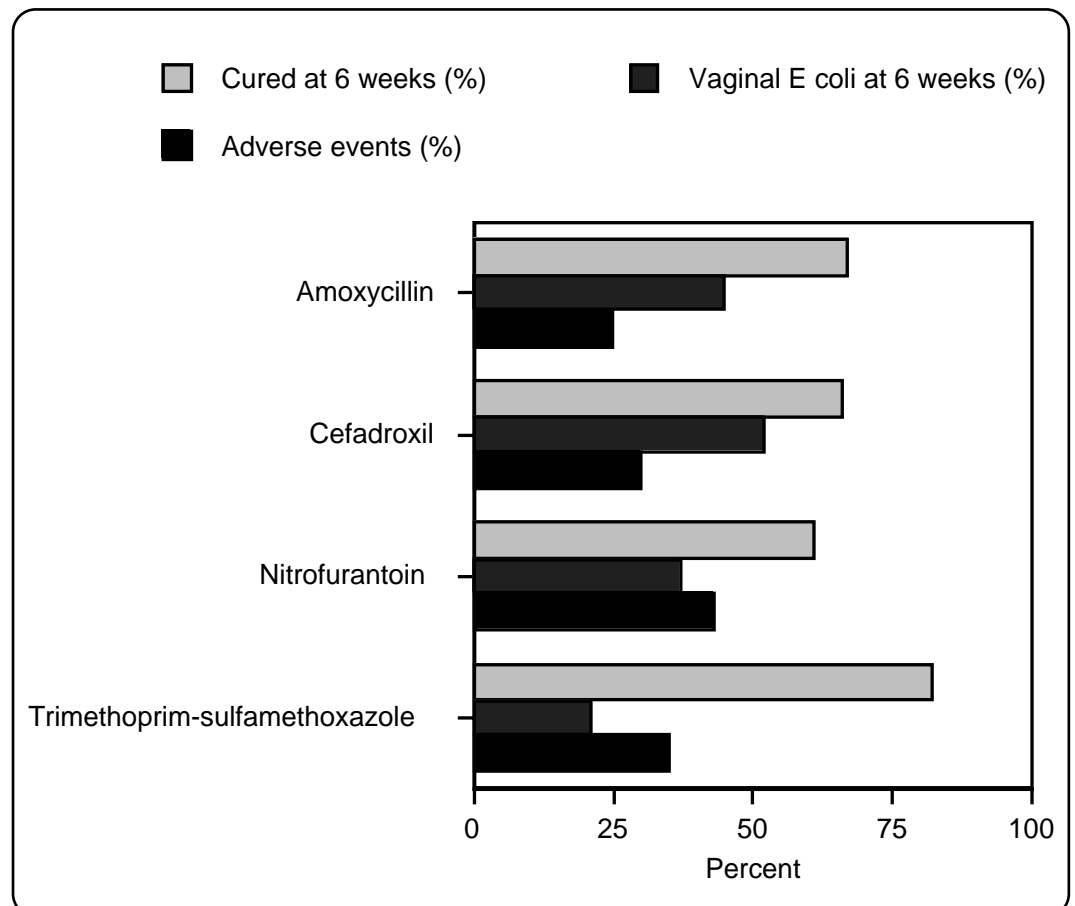
Though the results of this study would appear to be that the cheapest drug works best - and probably results in fewer women returning because of inefficacy - it is a classic example of US and UK practices differing. It is an excellent, well-conducted study.

The problem is that Co-trimoxazole may not be better than trimethoprim alone, and the combination may carry a higher rate of adverse effects, especially in the elderly. Prescribing policies in the UK favour trimethoprim alone.

More on this subject is to be found in *Bandolier* 15.

## Reference:

TM Hooton, C Winter, F Tiu, WE Stamm.  
Randomized comparative trial and cost analysis of 3-day antimicrobial regimens for treatment of acute cystitis in women. *Journal of the American Medical Association* 1995 273: 41-5.



## EVIDENCE-BASED INFORMATION

*Bandolier* tries to bring new sources of evidence-based information to its readers. We are delighted that Iain Chalmers has drawn our attention to a new quarterly Canadian publication which is of considerable interest.

Called "informed" (ISSN 1201-2475), it is published by the Institute of Clinical Evaluative Sciences in Ontario. About the length of *Bandolier*, it has the same theme of helping to make evidence-based clinical decisions.

### Ankle rules, OK!

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Issue 1 in November 1994 contains a classic report on the Multicentre Ankle Rules Study. This tested a decision aid algorithm in eight hospitals in Ontario; 200 physicians learned the rules and applied them to over 5,000 adult patients with ankle injuries. The results were impressive: a 26% reduction in the number of ankle X-rays and an 11% reduction in the number of foot X-rays, with no increase in the number of fractures missed.

### Dr No and Dr Go

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Another fascinating item is 'stories from the front lines'. In the first issue there is a simple description of a problem facing a small community hospital with an imminent fiscal crisis which could only be met by closing operating rooms and inpatient beds. The solution to this familiar problem was interesting.

From 65 practising clinicians, 10 "wise persons" were chosen to serve as Dr No; any clinician wishing to admit on an emergency basis to a vacant bed would have first to discuss the admission with Dr No, examining the proposed plan of management and any alternatives.

Other clinicians had to become Dr Go. Two such clinicians toured the wards to discuss with doctors and nurses which patients could be discharged today, tomorrow, and so on.

In the five weeks this scheme operated during the crisis no elective surgery was cancelled for lack of a bed, nobody slept overnight in the emergency department and nobody was transferred to another hospital for lack of a bed. The bed management policy (the "tiny perfect hospital") was continued: 110 adult beds have been reduced to 45 with still no bed problems.

*Bandolier* wishes that it could reprint the diagrams and rules from the ankle study - they are simple and easy to put into practice. The study is as yet unpublished, so those wanting to know more should make sure they obtain this most useful publication, which is backed up by background information available by fax or mail. It can be obtained from:-

*Informed*  
G-106, 2075 Bayview Avenue  
Toronto, ON M4N 3M5  
Canada.  
Tel: (416) 480-6747

## CORTICOSTEROIDS FOR FOETAL MATURATION

### NIH consensus conference

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The use of antenatal corticosteroids for foetal maturation in preterm infants has been carried before in *Bandolier* in relation to a GRiP project in Oxfordshire (*Bandolier* #2, March 1994). The report on the NIH consensus conference on this subject has just been reported in JAMA [1]; while the conclusions are not different, this will be useful information for those engaged in the practice of evidence-based medicine.

The conference asked and sought to answer seven questions, and, as usual for NIH consensus conferences, did the job thoroughly. This was important for the USA, where only 15% of the 106,000 babies born weighing less than 2,000 grams are treated with corticosteroids. Though judging the economic consequences of treatment are difficult, the conference estimated that cost savings of about \$3,000 would result from each treated neonate, and increasing the proportion treated from 15% to 60% would result in savings of about £160 million in the USA.

The conference made a number of recommendations for the use of antenatal steroids, and these are shown in the box.

### The Grand Canyon

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It is obviously extremely important for the NIH to have had a consensus conference on steroids and foetal maturation, but one has to ask, perhaps, why it has taken so long, even though it is a welcome addition to the movement for evidence-based medicine.

The first RCT on the effects of giving a short course of corticosteroids to women expecting to give birth prematurely was reported in 1972. The Cochrane Collaboration logo summarises the evidence that would have been revealed had a systematic review of available RCTs been performed a decade later in 1982. Those who have seen the logo will notice a diamond lying to the left of a vertical line which indicates no effect; this marks that the result produced significant benefit when the results of seven trials were combined.

The reality was that it was 1989 that a systematic review of the RCTs had been prepared and published, but the problem seems to be that uptake of knowledge is very slow.

### British grand canyon

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There always seems to be a yawning gap between the knowledge that is available and the implementation of that knowledge. This can be seen in the UK as well as the USA.

Even when the knowledge on corticosteroids is available as beautifully as it is on the Oxford Database of Perinatal Trials produced by the Cochrane Collaboration, it seems not to be available where it is needed, as a survey of obstet-

## NIH RECOMMENDATIONS FOR THE USE OF ANTENATAL CORTICOSTEROIDS

- The benefits of antenatal administration of corticosteroids to foetuses at risk of preterm delivery vastly outweigh the potential risks. These benefits include not only a reduction in the risk of respiratory distress syndrome (RDS) but also a substantial reduction in mortality and intraventricular haemorrhage (IVH).
- All foetuses between 24 and 34 weeks gestation at risk of preterm delivery should be considered candidates for antenatal treatment with corticosteroids.
- The decision to use antenatal corticosteroids should not be altered by foetal race or gender or by availability of surfactant replacement therapy.
- Patients eligible for therapy with tocolytics should also be eligible for treatment with antenatal corticosteroids.
- Treatment consists of two doses of 12 mg of betamethasone given intramuscularly 24 hours apart or four doses of 6 mg of dexamethasone given intramuscularly 12 hours apart. Optimal benefit begins 24 hours after initiation of therapy and lasts seven days.
- Because treatment with corticosteroids for less than 24 hours is still associated with significant reductions in infant mortality, RDS and IVH, antenatal corticosteroids should be given unless immediate delivery is anticipated.
- In preterm premature rupture of membranes at less than 30 to 32 weeks gestation in the absence of clinical chorioamnionitis, antenatal corticosteroid use is recommended because of the high risk of IVH at these early gestational ages.
- In complicated pregnancies where delivery before 34 weeks gestation is likely, antenatal corticosteroid use is recommended unless there is evidence that corticosteroids will have an adverse effect on the mother or delivery is imminent.

Availability and use of the Oxford Database of Perinatal Trials in obstetric units in England		
	Teaching Hospitals (N = 24)	District Hospitals (N = 74)
	Number (%)	
Database <b>unavailable</b>	9 (38)	62 (84)
Database available	15 (62)	12 (16)
Used for:		
Planning research	8	1
Finding references	11	6
Education	13	7
Designing protocols	10	8
Specific patient problems	2	6
Unknown	1	2

ric units in England has shown [2]. Sara Paterson-Brown and her colleagues conducted a telephone survey of all 24 teaching hospitals and 74 of 173 district hospitals in England to about knowledge and implementation of the Database.

The results are shown in the table above. The Database was unavailable in 38% of the teaching hospitals and 84% of the district hospitals. The number of hospitals which used it to formulate policy through protocol design or to handle specific patient problems was disappointingly small.

Perhaps things have changed since 1993.

## References:

- 1 Effect of corticosteroids for fetal maturation on perinatal outcomes. Journal of the American Medical Association 1995 273: 413-8.
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# HEART DISEASE

Evidence of effectiveness of interventions for secondary prevention and treatment of coronary heart disease in primary care could be described as being just what the doctor ordered. Fortunately that order has been filled with a new and accessible publication commissioned by the Anglia & Oxford RHA and written by Michael Moher.

The main report is about 80 pages long. It covers:-

- Acute myocardial infarction
- Post-myocardial infarction
- Chronic stable angina
- Unstable angina
- Chronic heart failure
- Atrial fibrillation.

Michael Moher has done an admirable job. Each section covers topics like diagnosis and incidence, and the various treatment options. There is a summary of clinical practice implications and, most importantly, the quality of the evidence for each intervention is clearly laid out for the reader to perform his or her own weighting of the results. There are also copious references to key papers for further reading.

*Bandolier* would like to précis the document, but it is so tightly written that this is hardly possible. In fact, it is not even necessary, because a short nine page summary with all the salient conclusions is also available.

“Evidence of effectiveness of interventions for secondary prevention and treatment of coronary heart disease in primary care: A review of the literature” is available in full or in summary. Both can be obtained from Sue Weston, Anglia & Oxford RHA, Old Road, Headington, Oxford OX3 7LF.

Tel: 01865 226873

Fax: 01865 226959

The cost of the main document is £10 per copy, and the summary document is £5.